REMARKS

Claims 75, 97, 99-101, 111, 112, 122, 129, and 132 were pending in this application before entry of the amendments made herein. By this amendment, claim 75 has been amended to clarify the invention by addition of the proviso that the HSP-α2M receptor-related disorder is not Alzheimer's disease, but is an autoimmune disorder.

Written description support for the amendment to claim 75 is found in the specification as originally filed (for example, at page 7, lines 33-37; page 13, lines 5-16; and page 51, lines 8-10). Support for the proposition that claims can be properly amended to exclude one or more species of a genus when the specification provides a generic disclosure of the genus and numerous species within the genus, including the species being excluded from the scope of the claim, can be found in *In re Johnson*, 558 F.2d at 1019 (*see also* § 2173.05(i) of the Manual of Patent Examining Procedure, Eighth Edition, Revision 3, August 2005, at page 2100-223). Here, the specification provides a generic disclosure of the treatment of HSP-α2M receptor-related disorders and conditions, and numerous species therein (see page 13, lines 5-16). According to *Johnson*, the claims can be properly amended to exclude methods of treating Alzheimer's disease.

As such, no new matter has been added by the instant amendment. Applicants respectfully request that the amendment and remarks made herein be entered into the record of the instant application.

I. THE CLAIM REJECTION UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

The rejection of claims 75, 97, 99-101, 111, 122, 129, and 132 under 35 U.S.C. § 102(e) ("Section 102(e)") as allegedly being anticipated by Strickland *et al.* (U.S. Patent No. 6,156,311) as evidenced by Weiner *et al.* (Nature. 2002 Dec 19-26;420(6917):879-84), Singh *et al.* (Gerontology. 1997;43(1-2):79-94), and D'Andre (Med Hypotheses. 2005;64(3):458-63) is maintained by the Examiner. Specifically, the Examiner alleges that Alzheimer's disease, although not fully characterized as being an autoimmune disease at the time of the invention, has been associated or characterized as being a disorder involving autoimmunity, and thus, the method performed by Strickland *et al.* (*i.e.*, the administration of anti-CD91 antibody) would treat an autoimmune disease.

Applicants respectfully disagree. Applicants point out that claim 75 has been amended, solely to expedite prosecution, to clarify that the HSP-α2M receptor-related disorder being treated is not Alzheimer's disease. Strickland *et al.* teaches a method of using

a low density lipoprotein (LDL) receptor-related protein (LRP) antibody for the treatment of Alzheimer's disease (see Abstract), and does not teach treatment of any disease other than Alzheimer's disease. Thus, the rejection is obviated.

Nevertheless, Applicants maintain their position that the Examiner's rejection was in error. Applicants respectfully submit that the Examiner has maintained the rejection based on a misunderstanding of the applicable case law.

1. The Legal Standard

a. Claim Construction

The words of a claim are generally given their ordinary and customary meaning, *i.e.*, "the meaning that the term would have to a person of ordinary skill in the art in question *at the time of the invention, i.e., as of the effective filing date of the patent application.*" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*), quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) ("A court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art *at the time of the invention.*") (emphasis added); *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1363 (Fed. Cir. 2005) (meaning of claim "must be interpreted *as of [the] effective filing date*" of the patent application) (emphasis added); and *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000) (same).

Patent claims must be read in view of specification, of which they are a part. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*); *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1315 (Fed. Cir. 2003) ("[T]he best indicator of claim meaning is its usage in context as understood by one of skill in the art *at the time of invention.*") (emphasis added).

Extrinsic evidence consists of all evidence external to the patent and prosecution history. *Markman*, 52 F.3d at 980. Extrinsic evidence such as dictionaries and treatises are among the many tools that can help determine the meaning of particular terminology to those of skill in the art of the invention. *Phillips*, 415 F.3d at 1318. While extrinsic evidence can shed light on relevant art, it is less significant than the intrinsic record consisting of the claim language, the specification and prosecution history in determining legally operative meaning of patent claim language. *Id.* at 1317.

b. Anticipation

The legal test for anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in possession of the invention. *W.L. Gore Associates v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984); *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985). To anticipate a patent claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d 1362 (Fed. Cir. 1999); *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999).

2. The Meaning of the Claims as Amended

The Examiner presumably believes that the specification does not indicate that Alzheimer's disease is not an autoimmune disorder. Further, the Examiner contends that "although Alzheimer's disease (AD) was not fully characterized as being an autoimmune disease at the time of the invention [citation], *subsequent* characterizations of the disease indicates that the disease is in fact an autoimmune disease [citing D'Andrea]" (see Office Action, sentence abridging pages 3 and 4). The Examiner adds that "others have *recently indicated* that Alzheimer's disease has characteristics associated with autoimmune disorders" (see Office Action, first sentence of first full paragraph on page 4).

However, Applicants submit that the Examiner has ignored the governing case law, discussed above, regarding how terms in a claim are construed. As made clear by cases such as *Phillips*, *Innova/Pure Water*, *PC Connector Solutions,* and *Schering*, terms in the claims, *e.g.*, "autoimmune disorder," are construed as they would be understood by one skilled in the art at the time of the invention. The meaning of a claim term is determined *at the time of the invention, i.e., as of the effective filing date of the patent application. Phillips*, 415 F.3d at 1313. In the Office Action mailed August 28, 2003, the Examiner cited Weiner *et al.* for the proposition that Alzheimer's disease is inherently an autoimmune disease (see Office Action, page 5, paragraph abridging pages 4 and 5). In the instant Office Action, the Examiner additionally cites to D'Andrea for the proposition that Alzheimer's disease is in fact an autoimmune disease (see Office Action, page 4, lines 1-2). Weiner *et al.* and D'Andrea, which are both published after the filing date of this application, do not represent the understanding of the skilled worker *at the time of the invention.* At the time of the invention, Alzheimer's disease was not classified as an autoimmune disorder (see discussion in the

Amendment Under 37 C.F.R. § 1.111 filed on November 26, 2003 at pages 6-8, incorporated by reference herein). Thus, as the skilled artisan would understand at the time of the invention, "autoimmune disorder," as used in the instant claims, does not include Alzheimer's disease.

Nevertheless, the claims have been amended to specify that the disorder being treated is not Alzheimer's disease. Thus, since Strickland *et al.* does not disclose the administration of an anti-CD91 antibody to treat a disease other than Alzheimer's disease, Strickland *et al.* does not teach or suggest each and every element of the claims.

In view of the foregoing, Applicant submits that claims 75, 97, 99-101, 111, 122, 129, and 132 are novel over Strickland *et al.* Withdrawal of the Section 102(e) rejection is respectfully requested.

II. THE CLAIM OBJECTION SHOULD BE WITHDRAWN

The Examiner objects to claim 112 as being dependent on a rejected claim. For the reasons discussed above, claim 112 depends on a claim that is novel over Strickland *et al.*, and thus, the Examiner's rejection should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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Enclosures